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10/646,292	08/22/2003	Oksana Penezina	57315 (45858)	9380
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BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/646,292 PENEZINA ET AL. Office Action Summary Examiner Art Unit Hai Vo 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 26 December 2007. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-22 and 48-58 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-22 and 48-58 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date ______.

Notice of Informal Patent Application

6) Other:

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1. The examiner's suggestion made in the previous Office Action mailed 07/23/2007 that incorporation of "consisting of" in the claim would be sufficient to remove Withham as prior art was improper. For these reasons, this Office action will be made non-final even though all of the art rejections are maintained.

- The 112 claim rejections, first paragraph have been overcome by the present amendment. However, the 112 claim rejections, second paragraph are maintained.
- New ground rejection is made in view of newly discovered reference to Remigy et al (US 2002/0161066).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 6 are in conflict with claim 1 because polyethylene glycol diacrylate (PEGDA) is not capable of a significant *preferential* absorption on a substrate as shown in the present specification (example 2 at page 19 of the present specification) although PEGDA is a difunctional acrylate molecule having a hydrophobic alkyl portion.
- The 112 claim rejections have been maintained for the following reasons.
 Applicants contend that PEGDA provides a significant preferential absorption on

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a substrate. The arguments are in complete contrast to the description provided at page 19, lines 10-15 of the original disclosure.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filled in the United States before the invention by the applicant for patent, except that an international application filled under the treaty defined in section 35(1a) shall have the effects for purposes of this subsection of an application filled in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 1-19, 21, 22, 48-52, and 55-57 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Callahan et al (US 4,976,897). Callahan teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is polyethylene membrane having a pore

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size of 0.02 to 0.04 µm (column 3, lines 30-35). The photocatalyst is 2-hydroxyl-2-methyl-1-phenyl-propan-1-one (column 3, lines 62-63). Callahan teaches a UV curable resin comprising Celrad 3700-20T which is a composition of 20% trimethyol triacrylate dilution of dicracylate ester bisphenol A epoxy resin. Both trimethyol triacrylate and dicracylate ester bisphenol A epoxy resin are difunctional surface modifying molecules. Hence, the polymerization of the UV curable resin would form a crosslinked hydrophilic polymeric network consisting of the difunctional surface modifying molecules at the surface of the membrane. Callahan discloses the use of acrylic acid as a hydrophilic monomer, which reads on Applicants' negatively charged group. Callahan discloses the use of dimethylaminoethyl methacrylate as a hydrophilic monomer, which reads on Applicants' positively charged group. There is no pore plugging upon coating and curing (abstract). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Callahan was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. The coating comprises diacrylate ester of bisphenol A epoxy resin (table 1), which reads on Applicants' difunctional surface-modifying molecule. The UV resin is present in an amount of 1 to 99 wt% (column 3, lines

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50-55 and column 4, lines 50-55). Since Callahan discloses the amount of the UV resin could be used down to 1wt%, which read on Applicants' "less than about 1 wt%" because to the examiner, "about" means \pm 10% of the range, namely less than 1.1 wt% or less than 0.9 wt%. Alternatively, since the concentration is recognized as a result-effective variable, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical or provides unexpected results. Therefore, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the UV resin in an amount of less than 1 wt% in view of cost effectiveness, permeability/selectivity of the coated membrane. This is in line with $\ln re Aller$, 105 USPQ 233 which holds discovering the optimum or workable ranges involves only routine skill in the art.

Callahan does not specifically disclose the membrane is autoclavable. However, it is a product-by-process limitation not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Callahan is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity as discussed above. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same

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as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the membrane of Callahan.

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- 10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al (US 4,976,897) as applied to claim 1 above, and further in view of Steuck et al (US 4,618,533). Callahan does not specifically disclose the microporous substrate being polyvinylidene fluoride. Steuck, however, teaches a porous membrane for use in separation comprising a porous membrane including polyethylene and polyvinylidene fluoride (column 2, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute polyvinylidene fluoride for the polyethylene of the Callahan invention since two polymers have been shown in the art to be recognized equivalent porous membranes in separation processes.
- 11. The art rejections over Callahan have been maintained for the following reasons.
 Applicants contend that Callahan does not teach or suggest a composite porous

membrane comprising a hydrophobic substrate coated with difunctional surface modifying molecules wherein the surface modifying molecules are polymerized and crosslinked by UV radiation to form a crosslinked polymeric network consisting of the difunctional surface modifying molecules at the surface of the membrane. The examiner respectfully disagrees. Callahan teaches a UV curable resin comprising Celrad 3700-20T which is a composition of 20% trimethyol triacrylate dilution of dicracylate ester bisphenol A epoxy resin. Both trimethyol triacrylate and dicracylate ester bisphenol A epoxy resin are difunctional surface modifying molecules. The polymerization of the UV curable resin would form a crosslinked hydrophilic polymeric network consisting of the difunctional surface modifying molecules at the surface of the membrane. Accordinally, the art rejections are sustained.

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12. Claims 1-9, 12-17, 19, 21, 22, and 48-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Witham et al (US 6,193,077). Witham teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is polyethersulfone membrane having a pore size of 0.1 to 20 μm (column 4, lines 28-30). The difunctional surface-modifying molecule comprises ethoxylated bisphenol A diacrylate which is present in an amount of 0.1 to 0.7 wt% (column 4, lines 50-52, column 5, lines 26-30). Witham discloses polymerization of the polyfunctional monomers causing the corresponding polymer to attach to the polyethersulfone membrane

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and the polyethylene oxide to form a non-extractable surface (abstract). Likewise, the polymerization of the polyfuncitonal monomers forms a crosslinked hydrophilic polymeric network consisting of the difunctional surface-modifying molecules at the surface of membrane. There is no pore plugging upon coating and curing (column 4, lines 5-8). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Witham was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. Witham discloses that the membrane is autoclavable (column 4, lines 10-15). Accordingly, Witham anticipates or strongly suggests the claimed subject matter.

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Steuck et al (US 4,618,533). Witham does not specifically disclose the microporous substrate being polyvinylidene fluoride. Steuck, however, teaches a porous membrane for use in filtration comprising a porous membrane including polyether sullfone and polyvinylidene fluoride (column 2, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute polyvinylidene fluoride for the polyethersulfone of the

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Witham invention since two polymers have been shown in the art to be recognized equivalent porous membranes in filtration processes.

- 14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Hu et al (US 5,209,849). Witham does not specifically disclose the use of a photoinitiator to achieve polymerization of the monomers over the entire surface of the membrane. Hu, however, discloses the use of DROCUR ® 1173 as a photoinitiator to achieve polymerization of the monomers over the entire surface of the membrane. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use UV treatment to achieve polymerization of the monomers over the entire surface of the membrane because UV treatment and plasma treatment have been shown in the art to be recognized equivalent treatments to impart hydrophilicity to a hydrophobic porous membrane.
- 15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of Wu et al (WO 00/50161). US 6,780,327 will be relied on as an equivalent form of WO 00/50161 for convenience. Witham does not specifically disclose the crosslinked coating having been modified with a positive charge. Wu, however, teaches a porous membrane for use in filtration comprising a porous membrane and a crosslinked acrylic coating having a pendant cationic group linked to the backbone of the coating (column 4, lines 1-5, 30-40). Therefore, it would have

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been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to provide the coated membrane suitable for filtration of fluids containing negatively charged materials.

- 16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witham et al (US 6,193,077) as applied to claim 1 above, and further in view of WO 00/50160. Hou et al (US 6,783,937) will be relied on as an equivalent form of WO 00/50160. Witham does not specifically disclose the cross-linked coating having been modified with a negative charge. Hou, however, teaches a porous membrane for use in filtration comprising a porous membrane and a cross-linked acrylic coating having fixed negative charge (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to provide the coated membrane suitable for filtration of fluids containing positively charged materials.
- 17. The art rejections based on Witham have been maintained for the following reasons. Note that the present amendment is not sufficient to remove Witham as prior art because Witham does disclose polymerization of the polyfuncitonal monomers causing the corresponding polymer to attach to the polyethersulfone membrane and the polyethylene oxide to form a non-extractable surface (abstract). Likewise, the polymerization of the polyfuncitonal monomers forms a crosslinked hydrophilic polymeric network consisting of the difunctional surface-

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modifying molecules at the surface of membrane. The coating consisting of difunctional surface-modifying molecules would remove Witham as prior art instead.

18. Claims 1-3, 5-7, 9, 12, 14, 16-22, and 48-57 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Charkoudian et al (US 2003/0077435). Charkoudian teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules. The hydrophobic substrate is polyvinylidene fluoride membrane having a pore size of 0.1 µm (paragraphs 86 and 174). The difunctional surface-modifying molecule comprises a polyfunctional monomer in an amount of 0.75% by weight (paragraphs 127, table 1-continued). There is no pore plugging upon coating and curing (paragraph 77). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Charkoudian was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. Charkoudian discloses that the membrane is autoclavable (paragraph 160). Accordingly, Charkoudian anticipates or strongly suggests the claimed subject matter.

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19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian et al (US 2003/0077435) as applied to claim 1 above, and further in view of Wu et al (WO 00/50161). US 6,780,327 will be relied on as an equivalent form of WO 00/50161 for convenience. Charkoudian does not specifically disclose the crosslinked coating having been modified with a positive charge. Wu, however, teaches a porous membrane for use in filtration comprising a porous membrane and a crosslinked acrylic coating having a pendant cationic group linked to the backbone of the coating (column 4, lines 1-5, 30-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising a cross-linked coating that has fixed negative charges motivated by the desire to provide the coated membrane suitable for filtration of fluids containing negatively charged materials.

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian et al (US 2003/0077435) as applied to claim 1 above, and further in view of WO 00/50160. Hou et al (US 6,783,937) will be relied on as an equivalent form of WO 00/50160. Charkoudian does not specifically disclose the cross-linked coating having been modified with a negative charge. Hou, however, teaches a porous membrane for use in filtration comprising a porous membrane and a cross-linked acrylic coating having fixed negative charge (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a coated membrane comprising

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a cross-linked coating that has fixed negative charges motivated by the desire to provide the coated membrane suitable for filtration of fluids containing positively charged materials.

- 21. The art rejections based on Charkoudian have been maintained for the following reasons. Applicants contend that Charkoudian discloses a membrane having a crosslinked terpolymer. This is in complete contrast to the prevention invention which is directed to the composite porous membrane comprising a hydrophobic substrate coated with difunctional surface modifying molecules wherein the surface modifying molecules are polymerized and crosslinked by UV to form a crosslinked hydrophilic polymeric network consisting of the difunctional surface modifying molecules at the surface of the membrane. The examiner respectfully disagrees. The arguments are not commensurate in scope with the claims. Nothing in the claims is required the coating not a crosslinked terpolymer. Charkoudian discloses the crosslinked terpolymer coating is a copolymer formed from dimethylacrylamide, diacetone acrylamide and methylene-bis-acrylamide. The terpolymer has a hydrophobic portion, a hydrophilic portion and at least two crosslinking active groups. Accordingly, the art rejections are sustained.
- 22. Claims 1-7, 9-13, 14, 21, 22, and 48-57 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Remigy et al (US 2002/0161066). Remigy teaches a composite porous membrane comprising a hydrophobic substrate coated with difunctional surface-modifying molecules (example 1, table 3, paragraphs 32 and 36). The

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crosslinking agent is present in an amount of 0.0267% by weight (example 1). The hydrophobic substrate is polyphenylsulfone membrane (paragraph 27). Remigy discloses the use of acrylic acid as a hydrophilic monomer, which reads on Applicants' negatively charged group. Remigy discloses the coating composition comprising vinvl pyridine monomer which reads on Applicants' positive charged group. There is no pore plugging upon coating and curing (paragraphs 11 and 21). Likewise, the pore sizes of the coated composite porous membrane are substantially the same as the pore size of the composite porous membrane before coating. Similarly, the flow rate through the pores of the coated membrane is substantially the same as the flow rate through the pores of the non-coated membrane. Since Remigy was using the same material for the difunctional surface modifying molecule as Applicants, it is the examiner's position that the preferential association, wetting characteristics would be inherently present. Remigy does not specifically disclose the membrane is autoclavable. However, it is a product-by-process limitation not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Callahan is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity as discussed above. Even though productby-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process

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claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the membrane of Remigy.

23. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Remigy et al (US 2002/0161066) as applied to claim 1 above, and further in view of Steuck et al (US 4,618,533). Remigy does not specifically disclose the microporous substrate being polyvinylidene fluoride. Steuck, however, teaches a porous membrane for use in separation comprising a porous membrane formed from polyvinylidene fluoride and polysulfone (column 2, lines 60-65). The porous membrane has pores with an average pore size of 0.2 microns. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute polyvinylidene fluoride for the polysulfone of Remigy since two polymers have been shown in the art to be recognized equivalent porous membranes in separation processes.

Conclusion

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24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/ Hai Vo Primary Examiner, Art Unit 1794